

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET  
HASSLE, ASTRAZENECA LP, and  
ZENECA INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.,  
AND ACTAVIS PHARMA, INC.,

Defendants.

Civil Action No. 3:14-cv-07263-MLC-TJB

ASTRAZENECA ABAKTIEBOLAGET  
HASSLE, ASTRAZENECA LP, and  
ZENECA INC.,

Plaintiffs,

v.

ANDRX LABS, LLC., ANDRX  
CORPORATION, and ACTAVIS, INC.,

Defendants.

Civil Action No. 3:14-cv-08030-MLC-TJB

ASTRAZENECA AB, AKTIEBOLAGET  
HASSLE, ASTRAZENECA LP, and  
ZENECA INC.,

Plaintiffs,

v.

PERRIGO COMPANY PLC, PERRIGO  
COMPANY, L. PERRIGO COMPANY,  
and PADDOCK LABORATORIES, LLC,

Defendants.

Civil Action No. 3:15-cv-01057-MLC-TJB

**JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

Pursuant to the Scheduling Orders entered in the above captioned cases and Local Patent Rule 4.3, Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, and Zeneca, Inc. (collectively, “Plaintiffs” or “AstraZeneca”); Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc. (collectively, “Actavis”); Defendants Andrx Labs, LLC., Andrx Corporation, Actavis, Inc. (collectively, “Andrx”); and Defendants Perrigo Company plc, Perrigo Company, L. Perrigo Company, and Paddock Laboratories, LLC (collectively, “Perrigo”) hereby submit their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 6,369,085 (“the ’085 patent”) and 7,411,070 (“the ’070 patent”) (collectively, the “patents-in-suit”).

### **I. Construction of Claim Terms on which the Parties Agree**

In accordance with Local Patent Rule 4.3(a), the parties agree that, for purposes of this case, the term below should be construed as follows:

<b>Term Identified for Construction</b>	<b>Applicable Claims</b>	<b>Joint Proposed Construction</b>
highly crystalline form	’085 patent, claims 2 and 4-12	having a higher crystallinity than any other form of magnesium salt of S-omeprazole disclosed in the prior art <sup>1</sup>

### **II. Proposed Constructions of Disputed Claim Terms**

In accordance with Local Patent Rule 4.3(b), each party’s proposed construction for the disputed claim terms is as follows:

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<sup>1</sup> Defendants reserve the right to contend at trial that this construction renders the claims in which this term appears invalid under 35 U.S.C. § 112.

<b>Term Identified for Construction</b>	<b>Applicable Claims</b>	<b>Plaintiffs' Proposed Construction</b>	<b>Actavis/Andrx's Proposed Construction</b>	<b>Perrigo's Proposed Construction</b>
the magnesium salt of S-omeprazole trihydrate	'085 patent, claims 1-12 '070 patent, claims 1-4	a trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole	the magnesium salt of S-omeprazole in crystalline form containing three molecules of water of crystallization per molecule of magnesium salt of S-omeprazole	crystals of the magnesium salt of S-omeprazole trihydrate, substantially free from magnesium salts of R-omeprazole and other forms of magnesium salts of S-omeprazole
characterized by the following major peaks in its X-ray diffractogram	'085 patent claims 1-12	identifiable by reference to an X-ray diffractogram that includes the major peaks below	exhibiting, within the range of normal experimental error, each of the following as major peaks in its X-ray diffractogram, each such peak falling within the range for relative intensity recited for that peak, such ranges being defined at Column 5, lines 28-39	having each of the referenced major peaks in its X-ray powder diffractogram within normal experimental error
represented by FIG. 1	'070 patent claims 2, 4	represented by Figure 1 of the '070 patent	exhibiting an x-ray powder diffractogram that is the same as Figure 1 of the '070 patent, within normal experimental error	having an X-ray powder diffractogram that is the same as Figure 1 of the '070 patent within normal experimental error

As required by Local Patent Rule 4.3(b), Exhibit A contains Plaintiffs' proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Plaintiffs intend to rely to support their proposed constructions or to oppose Defendants' proposed constructions.

As required by Local Patent Rule 4.3(b), Exhibit B contains Actavis's and Andrx's proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Actavis and Andrx intend to rely to support their proposed constructions or to oppose Plaintiffs' proposed constructions.

As required by Local Patent Rule 4.3(b), Exhibit C contains Perrigo's proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Perrigo intends to rely to support its proposed constructions or to oppose Plaintiffs' proposed constructions.

### **III. Significant or Dispositive Claim Terms**

Local Patent Rule 4.3(c) requires the parties to identify the terms whose construction will be most significant to the resolution of the case and any disputed terms whose construction will be case or claim dispositive or substantially conducive to promoting settlement.

The parties identify "the magnesium salt of S-omeprazole trihydrate" as being most significant to the resolution of the case.

### **IV. Anticipated Time Needed for the Claim Construction Hearing**

Plaintiffs estimate that the Claim Construction Hearing will require approximately 3 hours divided equally between Plaintiffs (1.5 hours) and Defendants (1.5 hours).

Defendants estimate that the Claim Construction Hearing will require approximately 3.5 hours, divided between Plaintiffs (1.5 hours), Perrigo (1 hour) and Actavis/Andrx (1 hour).

### **V. Identification of Witnesses for the Claim Construction Hearing**

At this time, the parties do not anticipate calling any witnesses at the Claim Construction Hearing, but Plaintiffs reserve their right to call witnesses in the event that any defendant calls a witness, and each Defendant reserves their right to call witnesses in the event that Plaintiffs call a witness.

Dated: August 19, 2015

Respectfully Submitted,

By: s/John E. Flaherty

John E. Flaherty  
Ravin R. Patel  
McCARTER & ENGLISH, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

Einar Stole  
Edward H. Rippey  
COVINGTON & BURLING LLP  
1201 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2401  
(202) 662-6000

*Attorneys for Plaintiffs AstraZeneca AB,  
Aktiebolaget Hässle, AstraZeneca LP, and  
Zeneca Inc.*

By: s/Christine I. Gannon

Liza M. Walsh  
Christine I. Gannon  
CONNELL FOLEY LLP  
One Newark Center  
1085 Raymond Blvd.  
19th Floor  
Newark, NJ 07102  
(973) 535-0500  
lwalsh@connellfoley.com  
cgannon@connellfoley.com

Stephen A. Maddox  
Jeremy J. Edwards  
MADDOX EDWARDS PLLC  
1900 K Street NW, Suite 725  
(202) 830-0707  
smaddox@meiplaw.com  
jedwards@maiplaw.com

*Attorneys for Defendants, Actavis Laboratories  
Fl., Inc., Actavis Pharma, Inc., Actavis Inc.,  
Andrx Labs, LLC and Andrx Corporation*

By: s/Melissa E. Flax

Melissa E. Flax  
Michael Cross  
CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.  
5 Becker Farm Road  
Roseland, New Jersey 07068  
Telephone: (973) 994-1700  
Facsimile: (973) 994-1744  
MFlax@carellabyrne.com  
MCross@carellabyrne.com

Steven H. Sklar  
Kenneth P. Spina  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza  
180 N. Stetson Ave., Suite 4900  
Chicago, IL 60601

Telephone: (312) 616-5600  
Facsimile: (312) 616-5700  
ssklar@leydig.com  
kspina@leydig.com

*Attorneys for Defendants, Perrigo Company  
plc, Perrigo Company, and L. Perrigo  
Company*